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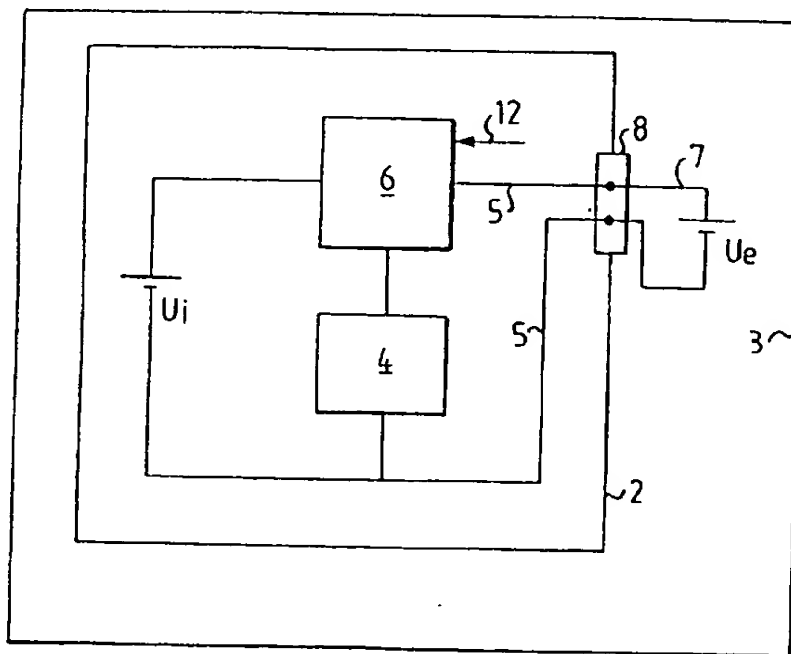
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(54) Title: ELECTRONICALLY OPERATED MEDICAL IMPLANT AND A STORAGE SYSTEM FOR SUCH AN IMPLANT

(57) Abstract

The application describes an electronically operated medical implant (2) provided with an electronic circuitry (4) for controlling the functions of said implant and an internal energy source (U_i) for powering said electronic circuitry (4) during operation. The implant also comprises an external energy receiving means (5, 9, 30) for receiving energy from an external energy source (U_e , 32, 46), and an energy source selecting means (6, 20, 22) for selecting the energy source (U_i , U_e , 32, 46) powering the implant, wherein said external energy receiving means (5, 30) is coupled to the electronic circuitry (4) for providing said electronic circuitry with energy from the external energy source (U_e , 32, 46) during storage. The application further describes a storage system containing a medical implant (2) as above, the storage system being adapted for storing said implant before implantation. The system comprises an external energy receiving means (5, 9, 30) for receiving energy from an external energy source (U_e , 32, 46) for providing the implant with energy during storage.



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ELECTRONICALLY OPERATED MEDICAL IMPLANT AND A STORAGE SYSTEM FOR SUCH AN IMPLANTTechnical Field of the Invention

The present invention relates to a medical implant arranged to be powered
5 during storage before use and a system for storing such medical implants before use.

Background of the Invention

Manufacturing and assembling of medical implants is carried out in strictly
10 clean environments. An assembled implant is normally sterilised and packed into a sterile package in which it is stored until the actual implantation into a patients body. An electronically operated implant, such as an implantable stimulator, which in its implanted position shall be electrically powered and independently operative, is therefore equipped with an internal energy source, for example a battery, in
15 connection with the assembling.

However, it often occurs that electronically operated implants are stored during a comparatively long period between the assembling and the implantation. Since the internal energy source of an electronically operated implant is connected to its electronic circuitry also during the storage, e.g. to supply energy to the
20 memory units of the implant, a certain amount of energy is constantly consumed.

Description of Related Art

In order not to drain the internal energy source to an unacceptable extent, such an electronically operated implant is often set in a low activity mode. Despite a
25 less than normal energy consumption in the low activity mode, the internal energy source will of course still be discharged to some degree already during storage. Presently, it is assumed that the internal energy source of for example an implantable stimulator shall have a charging enough for an operating time of about 5-7 years after implantation. After this operating time the internal energy source is

considered to be drained to such an extent that undisturbed operation of the stimulator cannot be warranted.

In prior art it is known to provide an implantable cardiac stimulator with a wirelessly rechargeable internal energy source in order to avoid changing the stimulator and thus to avoid a reoperation on the patient. Energy is then supplied
5 from an external source by means of induction via an electromagnetic energy transmitting coil positioned outside the patients body and an implanted energy receiving coil. Examples of prior art according to this principle is disclosed in US-A-4,134,408, US-A-4,166,470 and GB-A-2 239 802.

10

Problems in Prior Art

In practice, rechargeable implants are inconvenient for the patient due i.a. to the necessity of recurrent charging occasions and an inherent difficulty to control the electrical charge actually transferred to the implant. Therefore, the low activity
15 mode variety of electronically operated implants is today the most commonly used type.

As has been explained above, electronically operated implants thus consume energy already from the assembling and packing and onwards. Its operating time should therefore actually be calculated from the time of the assembling and
20 packing. However, since the storage time can be comparatively long it is therefore not likely that an electronically operated implant can be warranted undisturbed operation for as long as 7 years after implantation. A patient with such an implant must therefore be checked already after a shorter period of time.

Another aspect of low activity mode implants is the risk that the implant is
25 accidentally switched to the low activity mode during normal operation, for example due to an electromagnetic shock.

There is also a long-felt want to be able to stock a variety of electronically operated implants for a longer period of time in order to meet the needs of different patients. State-of-the-art electronically operated implants have however been

considered to be unsuitable for stock keeping due to the mentioned energy source drainage.

5 Summary

 The problem to be solved by the present invention is to maximise the possible operating time of an electronically operated implant after implantation in a patients body. An aspect of this problem is to prevent the internal energy source of such an electronically operated implant from being drained during storage. Another aspect
10 of the problem to be solved is to reduce the security risk of accidentally setting the implant in a non-operative mode by eliminating the need for a mode switching means in the implant.

 The basis for the present invention is the realisation of the possibilities to make use of the overall conditions in the storage phase of an active implant on one
15 hand and its operating phase on the other hand. Energy is generally easily accessible in the storage phase, whereas the implant must be made to rely on the limited energy store of its internal battery in the operating phase.

 According to the invention, the problem is solved by powering or energising the implant during storage with energy from an external energy source positioned
20 outside said implant with an implant having the features set forth in claim 1 and with a storage system as set forth in claim 5.

 An inventive system for storing electronically operated implants before implantation thus includes a package means and means for supplying an implant to be stored with energy from an external energy source. An implant of this inventive
25 system is typically provided with an electronic circuitry for controlling the functions of the implant and an internal energy source for powering the implant during operation. The implant further comprises means for receiving external energy coupled to the electronic circuitry for supplying said circuitry with energy from an external energy source, as well as an energy source selecting means for
30 selecting the energy source powering the implant. A package means for storing

implants of this system comprises means for powering an implant contained in said package means. A portable storing structure for storing a number of packed implants may also be provided within the inventive system, the portable storing structure comprising means for distributing energy to a plurality of implants
5 contained in said portable storing structure. The system may also include a non-portable storing structure comprising means for wireless, preferably inductive transmission of energy to stored implants, said means being placed in the vicinity of a space provided for said implants.

A combination of an implant and a package means is provided with means for
10 powering the implant contained in the package with energy from an external energy source positioned outside the implant.

Advantages

The warranted operating time of an implant stored in accordance with the
15 invention can be considerably prolonged and is at present expected to about 10 years instead of previous 5-7 years. Also the security risk of low activity mode implants is eliminated.

Further advantages and properties of the invention are apparent from the following description in connection with the accompanying drawings and the
20 dependent claims.

Brief Description of the Drawings

Fig 1A is a block diagram of an active implant which is connectable to an external energy source;

25 Fig 1B shows an embodiment of a combination of an active implant and a package means adapted for externally powering the implant;

Fig 2 and 3 show embodiments of selecting means comprised in implants for selecting internal or external powering;

Fig 4 and 5 show embodiments of an implant and a package means adapted
30 for wireless energy transmission from an external energy source to the implant;

Fig 6 shows a simplified example of electromagnetic energy transmission means; and

Fig 7 shows a portable and Fig 8 a non-portable storing structure for storing active implants, the storing structures being provided with means for externally
5 powering the implants.

Detailed Description

Fig 1A shows schematically an embodiment of an active implant 2 according to the present invention comprising an electronic circuitry 4 provided for the
10 normal operation of the implant, an internal energy source U_i , normally a battery, connected to the electronic circuitry 4. The implant 2, which for example may be a stimulator, such as a pacemaker or a defibrillator, or a distributor of medications, further comprises connection means 8 for input and output of electrical signals to and from the electronic circuitry 4. The implant is also provided with energy source
15 selecting means 6 arranged to selectively allowing energy supply from the internal energy source U_i or from an external energy source U_e which is connectable to the electronic circuitry via the connection means 8. The selecting means 6 is controllable for example via a control connection 12, and can be arranged either to diminish or to completely cut off energy flow from the internal energy source U_i .
20 In preferred embodiments of the invention the selecting means (6) is devised to automatically select powering from the an external energy source U_e dependent on the voltage or the current present when the external energy source is coupled to the implant. The implant further includes means for receiving energy from an external energy source, which in the example of fig 1A is represented by conductors 5
25 inside the implant and conductors 7 outside the implant.

In Fig 1A, the implant 2 is connected to an external energy source U_e via the connection means 8 and the selecting means 6 is thus arranged to switch from energy supply from the internal energy source U_i to energy supply from the external energy source U_e dependent on a control signal preferably provided by the
30 external energy source U_e itself via control connection 12. The selecting means 6

can for example be arranged such that it is activated when the external energy source U_e is connected to the implant 2 and a closed circuit comprising the electronic circuitry 4 and U_e is established, whereas the internal energy source U_i is switched into connection with the electronic circuitry 4 when U_e is disconnected.

5 The implant 2 can for example be a cardiac stimulator and the electronic circuitry 4 would then typically comprise a stimulation pulse generator, a heart rate monitor and perhaps a defibrillation circuit and a microprocessor for controlling the operations of the implant.

During storage the implant is packed in a sterile package and connected to an
10 external energy source U_e as described. In connection with the actual implantation the external energy source is disconnected from the implant and the internal energy source U_i turns into normal operation.

In implants that normally are provided with connection means 8 for input and output of electrical signals, such as cardiac stimulators having lead or electrode
15 connection means, the existing connection means is preferably modified to be capable of receiving energy for driving the electronic circuitry of the implant. This can be done for example by providing extra connectors for energy supply, or by using existing connectors supplemented with means for separating the normal
20 operation function from the energy receiving function when an external energy source is connected. In other embodiments of the invention, the implant may be provided with a separate, self tightening connector for one of the terminals of an external energy source and the other terminal may then be connected, for example
by means of a clip, to the housing of the implant which is arranged as common ground.

25 Fig 1B shows a combination of an implant 2 and a transport package 3, defined by enclosure wall means, for storing the implant before implantation. The package 3 of this embodiment is provided with energy receiving means 9 comprising conductors 7 and one or more connectors 11, the receiving means 9 being adapted to couple an external energy source U_e situated outside the package
30 3 to the implant 2. In other embodiments, the package is provided with a an

external energy source U_e positioned in the package, for example a battery, or energy receiving means comprising a receiving coil for electromagnetically transmitted energy.

Fig 2 shows an implant 2 with a first embodiment of the selecting means 20 comprising a first resistor R_e and a diode D coupled in series with the external energy source U_e and the electronic circuitry 4 via the connection means 8 in an external energy source loop. The energy source loop is via the selecting means 20 coupled in parallel with an internal energy source loop comprising the internal energy source U_i coupled in series with a possible resistor R_i and the electronic circuitry 4. The diode D is provided in the external energy source loop in order to avoid leakage currents from the internal energy source loop. With the voltages $U_e > U_i$ and the resistance of resistor R_e and of the possible resistor R_i chosen such that I_i is negligible, a balanced power supply which saves the internal energy source is achieved. Most commonly the battery voltage U_i is 2.8 V. The current level in the electronics of a stored pacemaker is 3 to 15 μA depending on the type of battery used. In a preferred embodiment the resistor R_e is selected to be large and U_e sufficiently large so as to obtain a construction which is more independent of the inaccuracy of the external energy source. In an example I_e is 7 μA , U_i 2.8V, the diode voltage 0.5 V and U_e 10V, and then the resistor R_e is selected to be 960 kohm.

Fig 3 shows an implant 2 with a second embodiment of the selecting means 22 such that the internal energy source loop, which again is coupled in parallel with an external energy source loop, is cut off when an external energy source U_e is connected to connection means 8. The selecting means 22 comprises a switch, in the shown embodiment in the shape of a transistor circuit where the drain connector 24 and the source connector 26 of a transistor T , in this embodiment exemplified by a P-channel MOS transistor, is coupled in series with a resistor R_i and the electronic circuitry 4 in an internal energy source loop. The gate connector 28 of transistor T is coupled to a switch control loop connected to an external energy source U_e and coupled in parallel with an external energy source loop connected to

the electronic circuitry 4. The switch control loop comprises a current generator 14 having a high internal impedance and a first diode D1 coupled in series with a resistor Re. When an external energy source Ue is connected to the selecting means 22, a voltage is imposed on the gate connector 28 and the current Ii of the internal energy source loop is thus cut off.

The external energy source loop comprises a second diode D2 coupled in series with the above mentioned resistor Re, the electronic circuitry 4 and the external energy source Ue for externally powering said electronic circuitry 4. The selecting means may also be provided with a stabilising capacitor 16 coupled in parallel with the electronic circuitry 4 for neutralising high frequency transients.

Fig 4 shows a block diagram of an implant 2 comprising selecting means 6, an electronic circuitry 4, an internal energy source Ui and energy receiving means 30 devised to receive electromagnetically or inductively transmitted energy from an energy transmitting means 32 positioned outside the implant and for externally powering the implant. The energy receiving means 30 is preferably coupled to the electronic circuitry 4 as explained above in connection with figures 1-3. Fig 5 shows a combination of an implant 2 and a package 3, wherein parts of the energy receiving means 30 is comprised in the transport package 3 and is coupled to the implant via connection means 8. Energy is transmitted from energy transmitting means positioned outside the transport package.

Since the necessary power depends on the normal unloaded electronics, and if the current level in a pacemaker is about 3 to 15 μA , then the necessary power would be about 8 to 42 μW , depending on the pacemaker type. Of course, the transferred power must exceed the necessary power so as to compensate for losses during the transmission and the energy transformation. Magnetic or electromagnetic energy transmission may be carried out from a few dozen kHz to a few dozen MHz.

An embodiment of the energy receiving means 30 and the energy transmitting means 32 situated at opposite sides of the implant housing wall or the enclosure wall means 35 is shown in Fig 6. The energy transmitting means 32 comprises a

high frequency generator 38 and a transmitting coil 40. The energy receiving means 30 comprises a receiving coil 36 a rectifier 42 and a stabiliser 44, and delivers when electromagnetic energy is transmitted an external energy voltage U_e for powering an external energy source loop in the implant as explained above.

- 5 In implants comprising transmission coils for telemetry, the existing telemetry coil may be utilised and adapted to energy receiving purposes according to the invention.

An embodiment of an inventive system for storing active implants is shown in Fig 7 and comprises a portable storing means, e.g. a box, 45 for storing active
10 implants 2 in their transport packages 3. The storing box 45 comprises a power unit 46 for distributing external energy to each implant 2. In one embodiment adapted for storing implants packed in transport packages 3 provided with connection means 9, the power unit 46 is connected to each implant 2 via conductors coupled to said connection means 9. The power unit 46 is preferably provided with a
15 connector 48 for connecting said power unit 46 to any mains power supply. In another embodiment, the power unit 46 may instead be provided with energy transmitting means (not shown) for electromagnetic energy transmission to combinations of implants 2 and transport package 3 comprising electromagnetic energy receiving means.

- 20 Fig 8 shows a schematic overview of another embodiment of a system for storing active implants. A non-portable storing structure 50, for example a cupboard or a set of shelves, is provided with energy transmitting means 32 devised for inductive transmission of energy and situated close to or in the vicinity of a space for storing implants in storing boxes 45. For example, the energy transmitting
25 means may be incorporated with a shelf 52.

Claims

1. An electronically operated medical implant (2) provided with an electronic circuitry (4) for controlling the functions of said implant and an internal energy source (Ui) for powering said electronic circuitry (4) during operation
5 **characterized in** that said implant also comprises an external energy receiving means (5,30) for receiving energy from an external energy source (Ue,32,46), and an energy source selecting means (6,20,22) for selecting the energy source (Ui,Ue,32,46) powering the implant, whereby said external energy receiving means
10 (5,30) is coupled to the electronic circuitry (4) for providing said electronic circuitry with energy from the external energy source (Ue,32,46) during storage.
2. An implant as recited in claim 1 **characterized in** that the energy source selecting means (6,20,22) is devised to limit or prevent energy flow from the
15 internal energy source (Ui) when an external energy source (Ue,32,46) is coupled to the energy receiving means (5,30).
3. An implant as recited in claims 1 or 2 **characterized in** that the external energy source (Ue) is a battery coupled to the implant (2) via said energy receiving means
20 (5,30).
4. An implant as recited in claims 1 or 2 **characterized in** said energy receiving means (30) is devised to receive wirelessly transmitted energy from the external energy source (32,46).
25
5. A storage system containing an electronically operated medical implant (2), and adapted for storing said implant before implantation, the implant being provided with an internal energy source (Ui) for powering the implant during operation
characterized in that said system further comprises an external energy receiving
30 means (5,9,30) for receiving energy from an external energy source (Ue,32,46) for

providing the implant with energy during storage and that said implant further comprises energy source selecting means (6,20,22) for selecting the energy source (U_i,U_e,32,46) powering the implant.

- 5 6. A storage system as recited in claim 5 **characterized in** that said energy source selecting means (6,20,22) is devised to limit or prevent energy flow from the internal energy source (U_i) when the external energy source (U_e,32,46) is coupled to the external energy receiving means (5,9,30).
- 10 7. A storage system as recited in claims 5 or 6 **characterized in** that said external energy source (U_e,32,46) is couplable to the external energy receiving means (5,9,30).
8. A storage system as recited in any of the claims 5-7 **characterized in** that said
15 external energy receiving means (5,30) is placed inside said implant.
9. A storage system as recited in any of the claims 5-7 **characterized in** that said external energy receiving means (5,9,30) is placed outside said implant.
- 20 10. A storage system as recited in any of the claims 5-9 **characterized in** that said system further comprises a package means (3) for containing said implant and said external energy receiving means (5,9,30), wherein said package means (3) is defined by enclosure wall means (35).
- 25 11. A storage system as recited in any of the claims 5-10 **characterized in** that said external energy source (U_e) is placed inside said package means (3).
12. A storage system as recited in claim 10 **characterized in** that said external energy receiving means (9) is couplable to the external energy source (U_e) through
30 the enclosure wall means (35) via a connectors (11) and conductors (7).

13. A storage system as recited in any of the claims 5-11 **characterized in the**
external energy source (32,46) is wirelessly couplable to the external energy
receiving means (30) and devised for wireless transmission of energy to the energy
5 receiving means (30).

14. A storage system as recited in claim 13 **characterized in that** said external
energy source (32) comprises a high frequency generator (38) coupled to a
transmitting coil (40) devised for inductive transmission of energy to a receiving
10 coil (36) comprised in the energy receiving means (30).

15. A storage system as recited in any of the claims 5-10 or 12-14 **characterized in**
that said system comprises a portable storing means (45) for containing a plurality
of implants (2) packed in package means (3), said external energy source (46)
15 being placed in said portable storing means (45) and devised for distributing
external energy to a plurality of contained implants.

16. A storage system as recited in any of the claims 5-10 or 12-14 **characterized in**
that said system comprises a non-portable storing means (50,52) for storing a
20 plurality of implants (2) in package means (3) wherein the external energy source
(32) is placed in the vicinity of a space provided for the implants (2).

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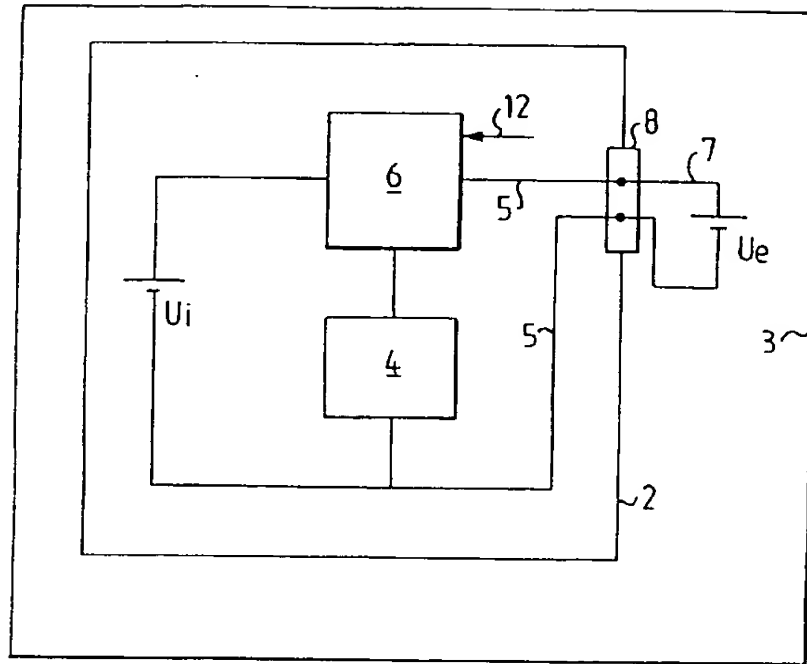


FIG. 1A

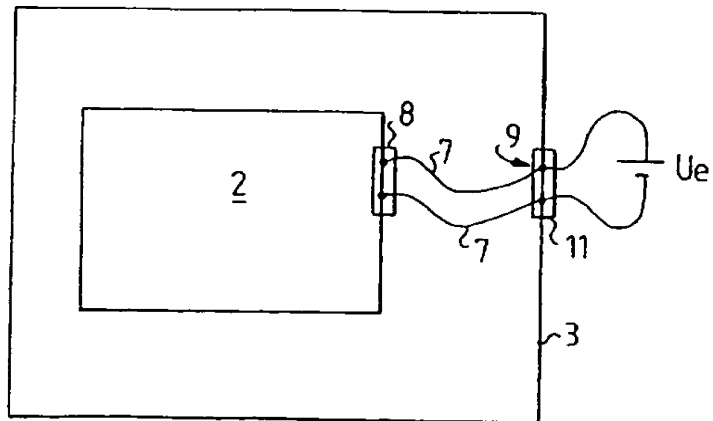


FIG. 1B

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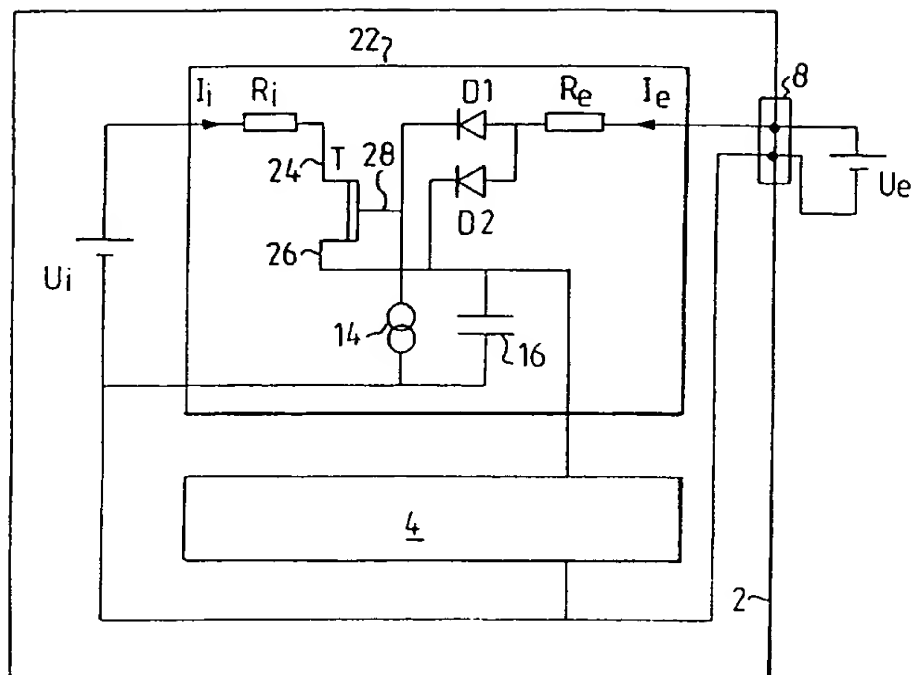


FIG. 3

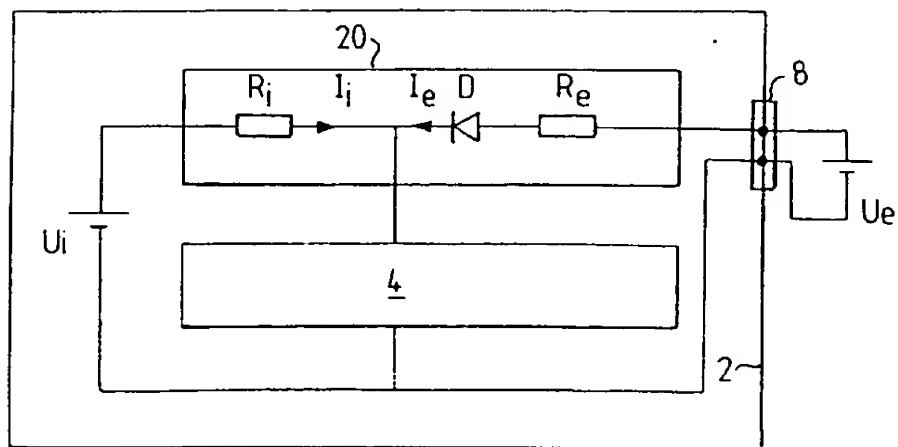


FIG. 2

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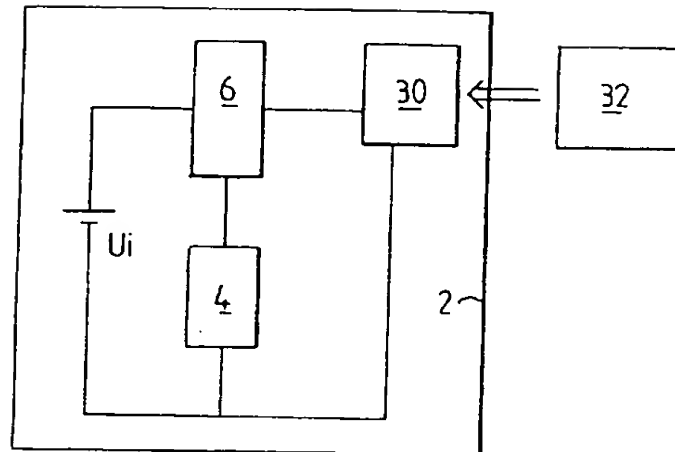


FIG. 4

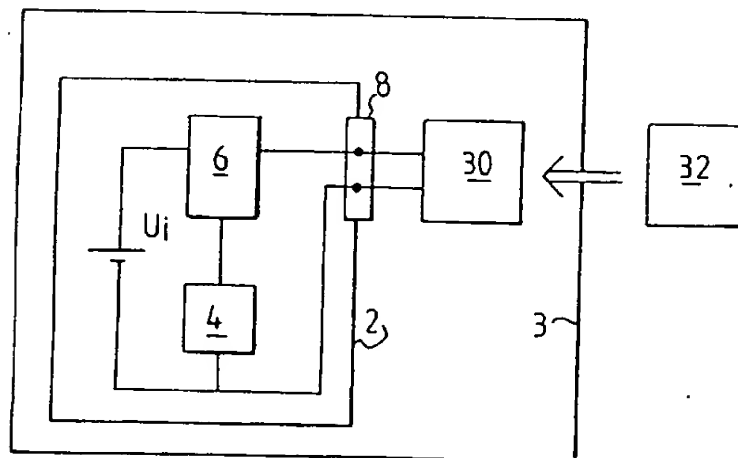


FIG. 5

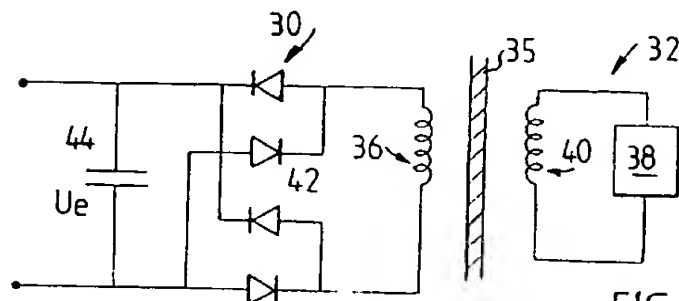
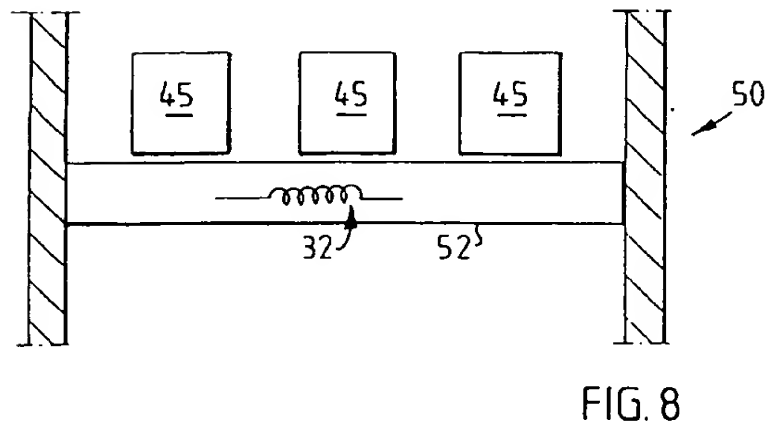
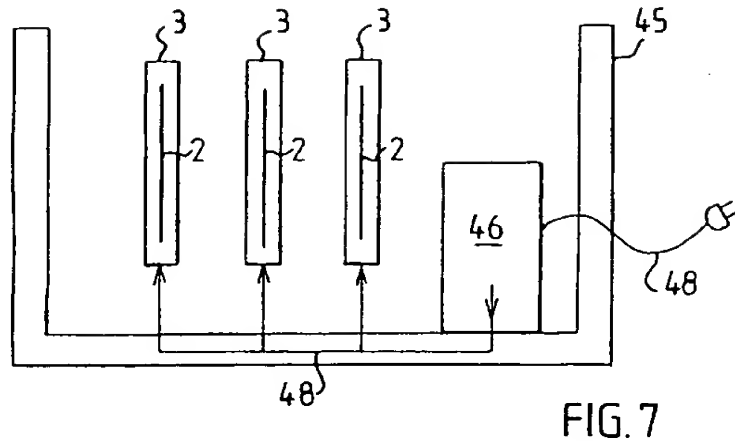


FIG. 6

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INTERNATIONAL SEARCH REPORT

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PCT/SE 97/01399

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61N 1/372, A61N 1/378

According to International Patent Classification (IPC) or to both national classification and IPC

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5370666 A (LINDBERG ET AL), 6 December 1994 (06.12.94), abstract --	1-16
A	US 4166470 A (NEUMANN), 4 Sept 1979 (04.09.79), column 5, line 8 - line 46 --	1-16
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Patent document cited in search report			Publication date	Patent family member(s)	Publication date
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